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Five years of aftercare of implant-retained mandibular overdentures and conventional dentures

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SUMMARY **The purpose of this multicentre randomized clinical trial was to analyse surgical and prosthetic aftercare and clinical implant performance of edentulous patients with implant-retained mandibular overdentures and of patients with conventional dentures, either or not after pre-prosthetic vestibuloplasty and deepening of the floor of the mouth. The evaluation period was 5 years. The implant systems evaluated were the IMZ implant system, the Brånemark implant system and the Transmandibular Implant system. The centre in Groningen had five groups (n = 149) and the centre in Nijmegen had three groups (n = 86). The evaluation comprised of surgical and prosthetic aftercare, together with clinical implant performance (CIP). The highest implant loss (29%) is found in the Transmandibular Implant group. All groups had prosthetic revisions and complications according to the CIP-scale. The majority of the patients in the endosseous implant groups were subject to minor complications. The CIP-score of the Transmandibular Implant group is significantly higher than the scores of the other groups, because of the high number of lost posts. In 26·1% of the patients in this group score 4 is given, which means failure of the implant system. From this study it can be concluded that the endosseous implant systems used in this study have less surgical aftercare and a better clinical implant performance than the Transmandibular Implant system and are therefore the systems of choice for the edentulous mandible.**

KEYWORDS: dental implant, overdenture, edentulous, aftercare

Introduction

Problems with lack of stability and retention of a lower denture can often be solved with the use of endosseous or transmandibular implants to which an overdenture can be attached. One of the first studies about overdentures retained by endosseous implants was published by Van Steenberghe *et al*. (1987). Also Maxson *et al*. (1989) on the use of transmandibular implants for retention of overdentures. Since then numerous articles have appeared dealing with this subject, concluding that it is a very successful therapy (Chao *et al*., 1995; Batenburg *et al*., 1998a). However, literature on prospective studies with a follow-up period of at least 5 years about overdentures retained by implants is limited to Mericske-Stern *et al*. (1994), Jemt *et al*. (1996), Kwakman *et al*. (1998), Naert *et al*. (1998) and Meijer *et al*. (1999). Many different endosseous implant systems have been used in prospective studies, all claiming high survival rates varying from 87 to 100% (Batenburg *et al*., 1998a). Comparison between different implant systems and conventional denture treatment is only possible in a randomized clinical trial (Antczak-Bouckoms & Chalmers, 1988; Barmes, 1990). There are some studies published with two or more different implant systems in one

prospective study: Mericske-Stern and Zarb (1993) with the Brånemark implant system* and the ITI Dental Implant system†, Geertman *et al.* (1996) with the Brånemark implant system, the IMZ implant system‡ and the Transmandibular Implant system§, Kwakman *et al.* (1998) with the Transmandibular Implant system and the IMZ implant system, Boerrigter *et al.* (1997) with the Brånemark implant system and the IMZ implant system, Batenburg *et al.* (1998b) with the Brånemark implant system, the IMZ implant system and the ITI Dental Implant system and Roynesdal *et al.* (1998) with a titanium plasma sprayed cylinder implant system, a titanium cylinder implant system with hydroxyapatite coating and a threaded titanium implant system (all 3i, Implant Innovations, Palm Beach Gardens). Observation time in these studies was 3 years or less except in the study of Kwakman *et al.* (1998) which was 5 years. The number of complications and the amount of aftercare related to the superstructure and prosthesis is important with respect to the choice of components. Some studies are known that address prosthetic aftercare (Hemmings *et al.*, 1994; Walton & MacEntee, 1994; Versteegh *et al.*, 1995; Watson *et al.*, 1997; Behr *et al.*, 1998). There are no studies on aftercare in which implant-retained overdentures and conventional dentures are evaluated within one study.

Aim of the present multicentre randomized clinical trial was to analyse surgical and prosthetic aftercare and clinical implant performance of edentulous patients with implant-retained mandibular overdentures and of patients with conventional dentures, either or not after pre-prosthetic vestibuloplasty and deepening of the floor of the mouth during a 5-year period.

Materials and methods

This study is part of a multicentre randomized clinical trial in which treatment effects of different implant systems retaining mandibular overdentures in patients with severely resorbed mandibles are compared with each other and with a control group, which was treated with a conventional denture, either or not after vestibuloplasty and deepening of the floor of the mouth. Two centres participated in this study: the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics (University Hospital Groningen, the Netherlands) and the Department of Oral Function and Prosthetic Dentistry/Department of Oral and Maxillofacial Surgery (University of Nijmegen, the Netherlands).

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Patient selection

Patients with persistent problems caused by reduced stability and insufficient retention of their lower denture were selected for the study. The patients were informed about the different treatment options, possible risks, and the method employed for assignment to the treatment groups. Informed consent was obtained from all participants. The study was approved by the hospital's Medical Ethical Committee. Inclusion criteria for the study were: edentulousness in upper and lower jaw for at least 1 year, problems with retention and stability of the lower denture, a mandibular bone height between 8 and 25 mm as measured at the symphysis on a lateral cephalometric radiograph and absence of former pre-prosthetic surgery or contraindications for a surgical procedure.

The two centres (Groningen and Nijmegen) made a different design for the study. The centre in Groningen had five groups ($n = 149$) and the centre in Nijmegen had three groups ($n = 86$) (Table 1).

Allocation to one of the treatments was executed by a computerized randomization balancing method to ensure pre-treatment comparability of the groups regarding age, gender, edentulous period in the lower jaw, number of previously made mandibular dentures, 'age' of the present lower denture and the mandibular bone height (Zielhuis *et al.*, 1990). There was no significant difference between the composition of the groups.

Surgical and prosthetic procedures

With the application of the IMZ implant system‡ and the Brånemark implant system* two implants were placed in the interforaminal region of the lower jaw (Brånemark *et al.*, 1985; Kirsch & Mentag, 1986). After a 3-month healing period abutments were placed during the second stage surgery. All patients received a single bar superstructure and an overdenture with clip attachment and a new denture in the upper jaw. With the application of the Transmandibular Implant system§ patients were operated under general anaesthesia

Table 1. Characteristics of the groups and participation

Group	Height of mandible (mm)	Treatment	Patients at the start of the study	Patients who died	Patients who did not show up for evaluation	Patients available for analysis of aftercare	Patients available for CIP-scale
Groningen							
Group 1	8–15	Two endosseous implants and overdenture	29	0	0	29	29
Group 2	8–15	Conventional complete denture	30	4	0	26	26
Group 3	16–25	Two endosseous implants and overdenture	32	2	0	30	30
Group 4	16–25	Vestibulumplasty and complete denture	28	1	0	27	27
Group 5	16–25	Conventional complete denture	30	3	1	27	26
Nijmegen							
Group 6	8–15	Transmandibular implant and overdenture	29	2	4	27	23
Group 7	8–15	Two endosseous implants and overdenture	29	1	2	28	26
Group 8	8–15	Conventional complete denture	28	0	0	28	28

(Bosker *et al.*, 1991). The day after surgery the superstructure was placed, consisting of a triple bar construction with two cantilever extensions. During a period of 3 months patients were not allowed to eat solid food nor to wear the lower denture. After this period an overdenture with multiple clips and a new upper denture was manufactured. The vestibuloplasty was carried out under general anaesthesia, according to the buccal onlay procedure as described by Hopkins (1987). Split thickness palatal graft, or a split thickness skingraft when a considerable amount of graft material was necessary, were used. Deepening of the floor of the mouth was performed according to Brown–Downton–Caldwell procedure (Stoelinga, 1984). After a healing period of 4 weeks, new complete dentures were made. The non-surgical control groups were treated by manufacturing a new set of dentures. A uniform prosthetic procedure with a balanced occlusion was performed for all patients.

All patients of the non-implant groups had to stick to the allocated treatment for at least 1-year. If patients were not satisfied with the initial treatment they had the opportunity to get implant-retained mandibular overdentures as well after 1-year. All patients were treated by experienced oral-maxillofacial surgeons and experienced prosthodontists.

Surgical aftercare

Surgical interventions were counted from the day of the implant operation procedure until 5 years after insertion. The following items were scored during the 5 years' follow-up:

(i) implant loss;

(ii) excision of gingival hyperplasia;

(iii) placement of palatal mucosa grafts around the implants;

(iv) postponed implant insertion in the conventional denture groups.

Prosthetic aftercare

Prosthetic items were taken into account from 6 months after placement of the prosthesis until 5 years after insertion of the implants. Prosthetic alterations within 6 months were attributed to errors in the clinical or dental laboratory procedure. The following items were scored:

Table 2. Surgical aftercare during 5 years of follow-up

Group	Height of mandible (mm)	Treatment	Implant loss (%)	Gingivectomy per patient	Palatal mucosa grafts per patient	Postponed implant insertion per patient (%)
Groningen						
Group 1	8–15	Two endosseous implants and overdenture	3 (5)	4	3	–
Group 2	8–15	Conventional complete denture	–	–	–	6 (23)
Group 3	16–25	Two endosseous implants and overdenture	10 (17)	1	1	–
Group 4	16–25	Vestibulumplasty and complete denture	–	–	–	3 (11)
Group 5	16–25	Conventional complete denture	–	–	–	8 (30)
Nijmegen						
Group 6	8–15	Transmandibular implant and overdenture	31 (29)	2	0	–
Group 7	8–15	Two endosseous implants and overdenture	0 (0)	6	1	–
Group 8	8–15	Conventional complete denture	–	–	–	10 (36)

(i) broken abutments or coping screw;
(ii) new or repair of bar and/or gold cylinders;
(iii) new clips or fastening of loose clips;
(iv) relining upper denture;
(v) relining lower denture;
(vi) repair denture base or denture teeth;
(vii) readjustment of occlusion;
(viii) new upper denture;
(ix) new lower denture.

Clinical Implant Performance scale

To compare different implant systems the Clinical Implant Performance scale (CIP-scale) is used (Milholland *et al.*, 1973; Geertman *et al.*, 1996; Boerrigter *et al.*, 1997; Van Waas *et al.*, 1997). Each complication has a rating on a five-point rating scale. The highest rating given to each patient is used for the analysis. The CIP-scale included the following ratings:
0 = success, no complications;
1 = minor complications;
2 = complications with a chance of recovery or stabilization of the present situation;
3 = serious complications that may lead to failure of the implant system;
4 = failure of the implant system.

Minor complications (CIP = 1) were gingival hyperplasia, relining of maxillary or mandibular denture, readjustment of occlusion, fracture of a cantilever extension (TMI), clip loosening, coping screw loosening (IMZ, Brå), broken abutment (IMZ, Brå), a slight disturbance of the mental nerve, X-ray score 0 along with probing depth ≥ 6 mm, X-ray score 1 along with probing depth ≤ 5 mm.

Complications with a chance of recovery or stabilization of the present situation (CIP = 2) were correction of a non-fitting superstructure, fracture of the superstructure, a severe disturbance of the mental nerve, fracture of one post (TMI), X-ray score 1 along with a probing depth ≥ 6 mm, X-ray score 2 along with a probing depth ≤ 5 mm.

Serious complications (CIP = 3) were scored in the case of removal of one post (TMI), an X-ray score 2 along with a probing depth ≤ 6 mm, X-ray score 3.

Failure of the implant system (CIP = 4) was scored in case of removal of two or more posts (TMI) or removal of one (or two) implants (IMZ, Brå) after the superstructure was placed.

For the X-ray score rotational panoramic radiographs were taken 5 years after functional loading of the implants. Possible bone loss around the implants was classified according to the following scale:
score 0 = No apparent bone loss;

Table 3. Prosthetic aftercare during 5 years of follow-up

Aftercare	Group 1 (two endosseous implants)	Group 2 (conventional denture)	Group 3 (two endosseous implants)	Group 4 (vestibu-lumplasty)	Group 5 (conventional denture)	Group 6 (transmandibular implant)	Group 7 (two endosseous implants)	Group 8 (conventional denture)
Broken abutment or coping screw	3	0	11	0	0	2	25	1
New/repair bar/gold cylinders	2	5	2	2	8	24	4	11
New clips/fastening loose clips	12	0	9	5	5	7	2	1
Relining upper denture	10	1	11	11	4	4	6	5
Relining lower denture	7	2	6	11	2	2	3	10
Repair denture base/teeth	16	4	17	18	13	4	3	2
Readjustment occlusion	8	4	5	6	4	2	2	5
New upper denture	0	2	0	2	5	2	0	3
New lower denture	1	6	1	2	7	3	0	7

score 1 = Reduction of bone level not exceeding one-third of the length of the implant;
score 2 = Reduction of bone level exceeding one-third of the length of the implant but not exceeding one-half of the length of the implant;
score 3 = Reduction of bone level exceeding one-half of the length of the implant;
score 4 = Total reduction of bone along the implant.

The probing depth was measured with a periodontal probe (Merit-B[††]) at four sites around the implants and the highest score was used for the analysis.

Data analysis

All scores were put into a database and a statistical analysis was done with the help of SPSS[††] 9·0. A significance level of 0·05 was chosen.

Results

Of the 235 patients who participated at the start of the study 13 patients died. This means that 222 patients were available for the analysis of aftercare during the entire 5 years. Seven patients did not attend the evaluation session because of sickness. So 215 patients were available for the calculation of the CIP-score (Table 1). The assumption was made that not attending the evaluation was independent of the clinical state or the amount of aftercare.

In Table 2 the surgical aftercare is denumerated during 5 years following implant insertion. The implant loss in the group which received a Transmandibular Implant system has been counted per post (one Transmandibular Implant has four posts). The highest implant loss (29%) is found in the Transmandibular Implant group.

The prosthetic aftercare has been listed in Table 3. The fewest revisions took place in group 2, a conventional denture group.

Table 4 lists the Clinical Implant Performance. None of the groups is without complications.

Discussion

Implant loss is one of the items of surgical aftercare (Table 2). There is significantly more implant loss (or

[**]Hu-Friedy, Chicago, Illinois, USA.
[††]Statistical Package Social Sciences, Version 9·0, SPSS Incorporated, Chicago, Illinois, USA.

Table 4. Clinical implant performance after 5 years of follow-up (percentage of scores)

Group	Height of mandible (mm)	Treatment	Score 0	Score 1	Score 2	Score 3	Score 4
Groningen							
Group 1	8–15	Two endosseous implants and overdenture	17·2	70·0	3·4	0·0	3·4
Group 2	8–15	Conventional complete denture	–	–	–	–	–
Group 3	16–25	Two endosseous implants and overdenture	20·0	70·0	3·3	0·0	6·7
Group 4	16–25	Vestibulumplasty and complete denture	–	–	–	–	–
Group 5	16–25	Conventional complete denture	–	–	–	–	–
Nijmegen							
Group 6	8–15	Transmandibular implant and overdenture	13·0	13·0	26·1	21·8	26·1
Group 7	8–15	Two endosseous implants and overdenture	11·5	46·2	15·4	26·9	0·0
Group 8	8–15	Conventional complete denture	–	–	–	–	–

loss of posts) in the Transmandibular Implant group (29%) than in the permucosal implant groups (5% in group 1, 17% in group 3 and 0% in group 7). The 5-year survival rate of the endosseous implant systems in group 1 and 7 are well in accordance with the studies of Mericske-Stern *et al.* (1994), Jemt *et al.* (1996) and Naert *et al.* (1998), with survival rates of 97, 94·5 and 99%, respectively. However, the survival rate in group 3 (83%) is deviating. These implants were placed in rather high mandibles (16–25 mm). A possible explanation for this low survival rate could be that in high mandibles a knife edge ridge has to be removed first to get enough width for the implants. This results often in loss of the upper cortical layer. Without cortical layer initial implant stability and uneventful healing is jeopardized. Comparison of the results of the Transmandibular Implant group with the 5-year analysis of Kwakman *et al.* (1998) reveals that the analysis per patient for TMI-implants is also high in this study: 26% of the patients lost one or more posts). Comparison with the study of Maxson *et al.* (1989) (retrospective, evaluation period 3 months to 5 years) learns that this study has 95·8% survival rate, the study of Bosker and Van Dijk (1989) (retrospective, evaluation period 6 months to 12 years) reveals a 97·8% survival rate and the study of Bosker *et al.* (1991) (retrospective, evaluation period 6 months to 13 years) states a survival rate of 96·8%. In these studies loss is noted per implant-system and not separately per post. It is therefore unclear how many posts are actually removed. A lower survival rate is mentioned in the retrospective study of Versteegh *et al.* (1995). They found a survival rate of TMI-posts of 74·8% after 5 years. This last result seems to be more comparable with the survival rate of this study. The number of gingivectomies and palatal mucosa grafts is low during the 5-year follow-up period. An average of 30% of the patients in the non-operated groups received implants after the 1-year evaluation was completed. In the group who received a vestibuloplasty and deepening of the floor of the mouth only 11% changed to an implant-retained overdenture. It is not known whether this group is more satisfied or if this group does not want another operation.

The prosthetic aftercare is listed in Table 3. Implant-related aftercare in patients of the non-implant groups who received implants after the 1-year evaluation has also been counted. The mean number of revisions is 2·0 per patient during the 5 years. Further analysis of broken abutments learns that almost in all cases this appeared to be the 4 mm high titanium connector of the 3·3 diameter IMZ-implant. With the 4·0 diameter implants no broken abutments occurred. The high number of new bars/gold cylinders in the TMI-group is

because of the high loss of posts. Every time a new post has been placed revision of the superstructure was needed. The new bars/gold cylinders in the originally non-implant groups is the result of the postponed insertion of implants, which has been counted as aftercare. This is also the case with the new lower dentures. In a number of cases a new denture has been made after insertion of implants, when the present denture could not be converted into an overdenture. Comparison with other studies with respect to prosthetic aftercare is difficult because literature on this subject is scarce and it concerns different implant systems, different attachment systems and a different follow-up period.

Analysing the CIP-scores (Table 4) it can be noticed that the majority of the patients in the endosseous implant groups were subject to minor complications (score 1). The scores in group 1 and group 3 are comparable, whereas the scores in group 7 are slightly different. Although none of the implants were lost, the bone loss in this group is responsible for the higher CIP-scores (compared with groups 1 and 3). There is no direct explanation why group 7 scores are worse than group 1, because the height of the mandible is the same in these groups. The only difference is the city where the treatment took place. The CIP-score of the Transmandibular Implant group is significantly higher than the scores of the other groups. This is caused by the high number of lost posts. In 26·1% of the patients score 4 is given, which means failure of the implant system.

From this study it can be concluded that:

(i) significantly more patients in the conventional denture groups chose for an implant-retained overdenture after 1-year than patients in the group who received a vestibuloplasty and deepening of the floor of the mouth as initial treatment;

(ii) the endosseous implant systems used in this have less surgical aftercare and a better clinical implant performance than the Transmandibular Implant system and are therefore the systems of choice for the edentulous mandible.

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